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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,322	04/05/2001	Laurent Schaller	6835-60067 (0800195-46)	5639

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EXAMINER

RAGONESE, ANDREA M

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,322

Applicant(s)

SCHALLER ET AL. CS

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 31-38 is/are rejected.
- 7) ☒ Claim(s) 36-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/14/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed on December 14, 2004 has been entered. Examiner acknowledges that **claims 1, 20, 24, 31 and 36**, as well as the specification, have been amended. Subsequently, **claims 1-26 and 31-38** are under consideration.

Drawings

2. The drawings were received on December 14, 2004. These drawings are acceptable.

Response to Arguments

3. Applicant's arguments, filed December 14, 2004, with regards to **claims 1-14, 20-23 and 31-35** have been fully considered but they are not persuasive.

Regarding the rejection of **claims 1-14, 20-23 and 31-35** under 35 U.S.C. 102(b) and in response to applicant's argument that "Wallace et al. never discloses a device or method for connecting two vessels or tissues together," a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the apparatus of the prior art of record (Wallace et al. in

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US 5,941,888) is **fully capable of attaching tissues**, and therefore, fully anticipates the instant invention.

In addition, specifically regarding the amendment to **claim 31**, the recitation "adapted to attach tissues" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Subsequently, the rejection of **claims 1-14, 20-23 and 31-35** is hereby made FINAL and reiterated hereinafter.

4. Applicant's arguments with respect to **claims 15-19, 24-26 and 36-38** have been considered but are moot in view of the new ground(s) of rejection.

Terminal Disclaimer

5. The terminal disclaimer filed on December 14, 2004 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent Nos. 6,613,059 and 6,641,593 and copending Application No. 09/828,335 has been received. However, this terminal disclaimer is awaiting review and acceptance by the Special Programs Examiner. Once this process has been completed, Applicant will be notified as to whether or not the terminal disclaimer has been accepted and recorded. Until such time, the obviousness-type double patenting

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rejection has been withdrawn pending further review and acceptance of the terminal disclaimer.

Claim Objections

6. **Claims 36-38** are objected to because of the following informalities: in **claim 36**, line 13, the term "memory" should be deleted and – member – inserted therefor. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1-14, 20-23 and 31-25** are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. (US 5,941,888).

Regarding **claim 1**, Wallace et al. disclose a tissue connector assembly having a surgical fastener having two clips (such as 102, 104, etc) fully capable of attaching tissues and a bridge portion (such as 106) connecting the two clips (such as 102, 104), as seen in figure 1.

Regarding **claim 2**, Wallace et al. disclose that as applied to **claim 1**, as well as, a bridge portion (such as 106) that is substantially straight, as seen in figure 1.

Regarding **claim 3**, Wallace et al. disclose that as applied to **claim 2**, as well as, two clips (such as 102, 104, etc.) that have an open configuration and a closed configuration, as discussed in column 5, lines 47-55.

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Regarding **claim 4**, Wallace et al. disclose that as applied to **claim 3**, as well as, a bridge portion that provides a predetermined spacing between the clips in the closed configuration, as discussed throughout the specification and seen in figure 1.

Regarding **claim 5**, Wallace et al. disclose that as applied to **claim 3**, as well as, at least one of the two clips (such as 102, 104, etc.) that is a self-closing clip, as recited in column 5, lines 47-55.

Regarding **claim 6**, Wallace et al. disclose that as applied to **claim 5**, as well as, a self closing clip that includes a shape memory material, as recited in column 5, lines 47-55.

Regarding **claim 7**, Wallace et al. disclose that as applied to **claim 5**, as well as, a coil (such as 102, 104) surrounding a substantial length of the self-closing clip (such as 102, 104).

Regarding **claim 8**, Wallace et al. disclose that as applied to **claim 5**, as well as, a closed configuration that is an unbiased configuration, as discussed in column 5, lines 47-55.

Regarding **claim 9**, Wallace et al. disclose that as applied to **claim 5**, a closed configuration is a loop, as seen in figure 5.

Regarding **claim 10**, Wallace et al. disclose that as applied to **claim 5**, as well as, an open configuration that is a biased configuration, and further having a release mechanism (such as a catheter) having a first position to bias the self-closing clip in the open configuration.

Regarding **claim 11**, Wallace et al. disclose that as applied to **claim 10**, as well as, a closed configuration is an unbiased configuration, and wherein the release mechanism (such as a catheter) has a second position (via a pusher as described in US 4,994,069) to unbiased the self-closing clip into the closed configuration.

Regarding **claim 12**, Wallace et al. disclose that as applied to **claim 11**, as well as, a coil (such as 102, 104) surrounding a substantial length of the self-closing clip, where the coil is coupled at one point on the self-closing clip and releasably coupled via the release mechanism at a second point on said self-closing clip.

Regarding **claim 13**, Wallace et al. disclose that as applied to **claim 12**, as well as, a first position that provides for compressing the coil between said first point and second point to form said biased configuration, via the deployment method.

Regarding **claim 14**, Wallace et al. disclose that as applied to **claim 13**, as well as, a second position that provides for releasably uncoupling the coil from said second point to form said unbiased configuration.

Regarding **claim 20**, Wallace et al. disclose a tissue connector assembly having a surgical fastener with two clips (such as 102, 104) fully capable of attaching tissues including at least one self-closing clip having an open configuration and a closed configuration, where the open configuration is a biased configuration and the closed configuration is an unbiased configuration, and a bridge portion (such as 106) having a substantially straight portion connecting the two clip and a release mechanism (such as a catheter) having a first position to bias said self-closing clip in the open configuration,

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and a second position to unbiased said self-closing clip into said closed configuration, as recited throughout the specification and seen in figures 1 and 5.

Regarding **claim 21**, Wallace et al. disclose that as applied to **claim 20**, as well as, a coil (such as 102, 104) surrounding a substantial length of said self-closing clip, where the coil is coupled at one point on the self-closing clip and releasably coupled via the release mechanism at a second point on the self-closing clip.

Regarding **claim 22**, Wallace et al. disclose that as applied to **claim 21**, as well as, a first position that provides for compressing said coil between the first point and second point to form the biased configuration.

Regarding **claim 23**, Wallace et al. disclose that as applied to **claim 22**, as well as, a second position that provides for releasably uncoupling the coil from the second point to form said unbiased configuration, via the deployment method.

Regarding **claim 31**, Wallace et al. disclose a surgical clip apparatus fully capable of attaching tissues having an elongated member, a pair of coils (such as 102, 104) surrounding at least a portion of the elongated member where the pair of coils are serially arranged and spaced from one another along the elongated member, as seen in figure 1. The elongated member is made of shape memory material and has an unbiased shape that includes a plurality of loops and a biased shape. The elongated member tends to move toward the unbiased shape to form the biased shape, as discussed in column 5 and seen in figures 1 and 5.

Regarding **claim 32**, Wallace et al. disclose that as applied to **claim 31**, as well as, loops that are spaced from one another, as seen in figures 1 and 5.

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Regarding **claim 33**, Wallace et al. disclose that as applied to **claim 32**, as well as, each coil that surrounds at least a portion of a different one of the loops.

Regarding **claim 34**, Wallace et al. disclose that as applied to **claim 31**, as well as, each coil that has an outer end and an inner end and the inner ends are spaced from one another, as seen in figures 1 and 5.

Regarding **claim 35**, Wallace et al. disclose that as applied to **claim 32**, as well as, each coil that has an outer end and an inner end and the elongated member has two enlarged portions, further including a restraint (such as 106) coupled to the elongated member adjacent to each of the inner ends, as seen in figure 1.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 15-19, 24-26 and 36-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz et al. (US 5,645,568) in view of Wallace et al. (US 5,941,888).

Regarding **claim 15**, Chervitz et al. disclose a tissue connector assembly having a surgical fastener (10) with two arms of a suture body (11) that is fully capable of clipping and attaching tissue and a bridge connecting the two clips and two ends including a first end and a second end, and further having two tissue piercing members (12) including a first tissue piercing member releasably coupled (can be cut/detached) to the first end and a second tissue piercing member releasably coupled to the second end. However, Chervitz et al. do not recite having two self-closing clips attached to the two arms of the suture body. However, use of two self-closing clips in a surgical fastening device was known at the time the invention was made. Specifically, Wallace et al. disclose a tissue connector assembly having a surgical fastener having two clips (such as 102, 104, etc) fully capable of attaching tissues and a bridge portion (such as

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106) connecting the two clips (such as 102, 104), as seen in figure 1. Therefore, it would have been obvious to modify the tissue connection device of Chervitz et al. to have the addition of two self-closing clips, as taught by Wallace et al., on either end of the suture body arms for the purpose of enhanced attachment of tissues.

Regarding **claim 16**, Chervitz et al. as modified disclose that as applied to **claim 15**. Further, a release mechanism, that activates the release of said two piercing members from said respective two ends would be obvious to one with ordinary skill in the art, for it has been held that to make something separable involves only routine skill in the art.

Regarding **claim 17**, Chervitz et al. as modified disclose that as applied to **claim 16**. Further, a release mechanism that activates the closing of said self-closing clip would be obvious given the combination.

Regarding **claim 18**, Chervitz et al. as modified disclose that as applied to **claim 15**, as well as, a suture, wherein the coupling of the first tissue-piercing member to the first end includes suture, and wherein the coupling of the second tissue-piercing member to the second end includes suture.

Regarding **claim 19**, Chervitz et al. as modified disclose that as applied to **claim 18**, as well as a suture of the first coupling and said suture of the second coupling are between about 10 mm and about 300 mm in length.

Regarding **claim 24**, Chervitz et al. disclose a tissue connector assembly having a surgical fastener (10) having two arms of a suture body (11) with two ends including a first end and a second end that is fully capable of clipping and attaching tissue, and a

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substantially straight bridge portion (such as 13) connecting the two arms; and two tissue piercing members (12) including a first tissue piercing member releasably coupled to the first end and a second tissue piercing member releasably coupled to said second end (can be cut/detached). However, Chervitz et al. do not recite having two self-closing clips attached to the two arms of the suture body. However, use of two self-closing clips in a surgical fastening device was known at the time the invention was made. Specifically, Wallace et al. disclose a tissue connector assembly having a surgical fastener having two clips (such as 102, 104, etc) fully capable of attaching tissues and a bridge portion (such as 106) connecting the two clips (such as 102, 104), as seen in figure 1. Therefore, it would have been obvious to modify the tissue connection device of Chervitz et al. to have the addition of two self-closing clips, as taught by Wallace et al., on either end of the suture body arms for the purpose of enhanced attachment of tissues.

Regarding **claim 25**, Chervitz et al. as modified disclose that as applied to **claim 24**. Further, a release mechanism that activates the release of the two piercing members from the respective two ends would be obvious to one with ordinary skill in the art, for it has been held that to make something separable involves only routine skill in the art.

Regarding **claim 26**, Chervitz et al. as modified disclose that as applied to **claim 25**. Further, a release mechanism that activates the closing of said self-closing clip would be obvious given the modification.

Regarding **claim 36**, as broadly and reasonably interpreted by the Examiner, the term “clip” is defined by *The American Heritage® Dictionary of the English Language, Third Edition* (copyright © 1992) as “any of various device for gripping or hold things together.” In this case, the surgical “clip” is broadly interpreted by the Examiner to be suture (10) because a suture is defined by *The American Heritage® Dictionary* to be “the fine thread or other material used surgically to close a wound or join tissues.” Therefore, the suture (10) is a surgical clip fully capable of attaching tissues. Chervitz et al. disclose a tissue connector apparatus having a surgical clip (10) with first and second piercing members (12) each having first and second end portions, first and second couplings and first and second flexible members (11). The clip has first and second end portion where the first coupling is coupled to the first end portion of the clip and the second coupling is coupled to the second end portion of the clip where the first flexible member has a first end portion coupled to the first coupling and a second end portion secured to the second end portion of the first tissue piercing member. The second flexible member has a first end portion coupled to the second coupling and a second end portion secured to the second end portion of the second tissue piercing member. Chervitz et al. do not recite an elongated member, a pair of coils surrounding at least a portion of the elongated member where the pair of coils are serially arranged and spaced from one another along the elongated member, the elongated member being shape member material and having an unbiased shape that includes a plurality of loops and a biased shape. The elongated member tends to move toward the unbiased shape from the biased shape. However, use of a pair of coils in a surgical fastening

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device was known at the time the invention was made. Specifically, Wallace et al. disclose a tissue connector assembly having a surgical fastener having a pair of coils (such as 102, 104, etc) being serially arranged and spaced from one another along said elongated member, wherein the elongated member tends to move toward the unbiased shape from the biased shape. Therefore, it would have been obvious to modify the tissue connection device of Chervitz et al. to have the addition of a pair of coils, as taught by Wallace et al., for the purpose of enhanced attachment of tissues.

Regarding **claim 37**, Chervitz et al. as modified disclose that as applied to **claim 36**. Further, a first coupling releasably coupled in the first end portion of the surgical slip to the first needle would be obvious to one with ordinary skill in the art, for it has been held to make something separable involves only routine skill in the art.

Regarding **claim 38**, Chervitz et al. as modified disclose that as applied to **claim 37**. Further, a second coupling couples the second end portion of the clip to a second needle would be obvious to one with ordinary skill in the art, for it has been held to make something separable involves only routine skill in the art.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

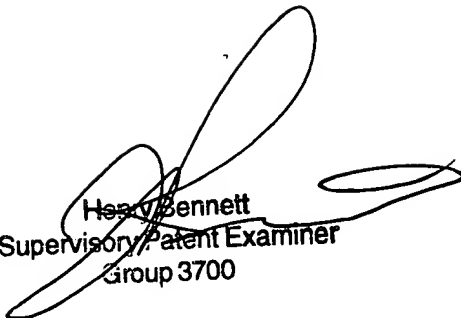
15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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AMR

March 7, 2005



Henry Bennett
Supervisory Patent Examiner
Group 3700